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10/519,678	01/07/2005	Takao Fujimura	264163US0PCT	9268
22850	7590	04/25/2007	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			MAKAR, KIMBERLY A	
		ART UNIT	PAPER NUMBER	
		1636		
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		04/25/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/25/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/519,678	FUJIMURA ET AL.	
	Examiner Kimberly A. Makar, Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 January 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
 - 4a) Of the above claim(s) 20-29 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-8, 18 and 19 is/are rejected.
- 7) Claim(s) 9-17 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 07 January 2005 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>03/04/05; 5/17/06</u> .	6) <input type="checkbox"/> Other: _____ .

DETAILED ACTION

Response to Arguments

1. Applicant's election with traverse of group I, claims 1-19 in the reply filed on 01/31/07 is acknowledged. The traversal is on the ground(s) that the examiner has (1) not provided sufficient reason or example to support patentable distinctness between the groups and (2) the examiner has not show a search burden exists in searching the entire application. This is not found persuasive because as stated in the original restriction dated 1/03/07, there was provided at least one example in each group where a distinction between the groups existed, either in composition, scope, or methodology. Furthermore, because the groups were distinct, comprising elements, reagents, and different scopes, a search for one group would not be co-extensive with a second group, therefore requiring additional searches. Thus since group I was distinct from groups II, III, IV, or V, a search of group I would not be co-extensive with groups II, III, IV, or V therefore requiring additional, burdensome searches.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 20-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 01/31/07.

Priority

3. Receipt is acknowledged of a certified copy of the PCT application referred to in the oath or declaration or in an application data sheet. If this copy is being filed to obtain the benefits of the foreign filing date under 35 U.S.C. 119(a)-(d), applicant should also file a claim for such priority as required by 35 U.S.C. 119(b). If the application being examined is an original application filed under 35 U.S.C. 111(a) (other than a design application) on or after November 29, 2000, the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. See 37 CFR 1.55(a)(1)(i). If the application being examined has entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and Regulations of the PCT. See 37 CFR 1.55(a)(1)(ii). Any claim for priority under 35 U.S.C. 119(a)-(d) or (f) or 365(a) or (b) not presented within the time period set forth in 37 CFR 1.55(a)(1) is considered to have been waived. If a claim for foreign priority is presented after the time period set forth in 37 CFR 1.55(a)(1), the claim may be accepted if the claim properly identifies the prior foreign application and is accompanied by a grantable petition to accept an unintentionally delayed claim for priority. See 37 CFR 1.55(c).

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4. However, applicant has failed to provide an English translation of the PCT application PCT/JP03/08621. The MPEP §1893 states that a copy of the international application is required for national stage entry into the United States, and if that PCT application was in another language other than English, an English translation of the PCT application must be furnished to the United States Patent office. Thus applicant is required to provide an English translation of PCT/JP03/08621 in order to maintain priority of the PCT application.

Drawings

5. The drawings are objected to because figure 11 contains a foreign language symbol in the X axis legend. Corrected drawing sheet of figure 11 in compliance with 37 CFR 1.121(d) is required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either

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"Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. A substitute specification for the claims is required pursuant to 37 CFR 1.125(a) because the original specification is not in proper idiomatic English, including run-on sentences and missing articles. Examples of improper idiomatic English include:

From the study of such action mechanism, it has become apparent that the expression of IL-2 gene at the transcriptional level is inhibited in the activated T-cells to suppress the rejection of the graft in organ transplantation, and this is very important in obtaining a therapeutic effect in various autoimmune diseases. (pages 1-2)

In this connection, it has been known that a series of histone deacetylases (hereinafter referred to as HDAC) that catalyze histone deacetylation work competitively with histone acetylases in a cell nucleus to control the expression level of various genes through alteration of the chromatin structure. As the results of so far energetic screening, a large number of HDAC-inhibitory compounds have been provided, which include compounds remarkably inhibiting the production of IL-2 (I. Takahashi et al., (1995) The Journal of Antibiotics 49, 453-457) and have attracted a considerable attention as candidates of~ immunosuppressive agents complementing cyclosporin A and tacrolimus. In fact, among thus chosen compounds, some ones showing an excellent *in vivo* immunosuppressive effect have been found. For example, as disclosed in WO 00/08048, FR225497 has been found to show an excellent effect as a therapeutic or preventive agent for organ transplant rejection or autoimmune diseases through the potent immunosuppressive effect, and in addition, it is suggested to have usefulness as a therapeutic or preventive agent for many other diseases which are considered to onset due to abnormal expression of genes. (page 2)

GATA-1 is a DNA binding protein which recognizes a (A/T)GATA(A/G) consensus sequence characteristically existing in the transcriptional region of hemopoietic gene. (page 3)

In Gata-1 protein, there are 2 sites of C4-type Zn (zinc) finger region. (page 3)

Correspondingly, there are 2 first exons in this gene. In these exons, it is said that IT promoter specifically acts in the testicle Sertoli cells and IE promoter act mainly in hematopoietic cells. However, it has been reported that IT promoter also acts at the step of differentiation of primary erythroid cells (A.M. Vannucchi et al., (1999) Journal of Cellular Physiology 180, 390-401), but it has not yet been elucidated fully how the 2 promoters are chosen *in vivo* for action. (page 4)

7. A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Claim Objections

8. Claims 8-17 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 8-17 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-7 and 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 1-6,18-19 recite the phrase, "immunosuppressive agent" which is not defined in the instant claims nor in the specification. While the specification gives examples of known immunosuppressive agents, such as cyclosporine A, etc. there is no definition of what an agent actually does in order to meet the qualifications of an "immunosuppressive agent." How suppressive does it have to be? What immune response is being suppressed? Is the suppression on the cellular level, where there is not activation of B-cells or T-cell? Is one type of cell activated but not another? Are macrophages involved? Is the expression of MHC molecules inhibited? Are there cellular markers that have to be up-regulated or down regulated for these agents to qualify as "immunosuppressive agents?" Is there a systemic requirement where a transplant recipient fails to reject a donor organ permanently? For how long? The specification teaches an animal model where a transplant is considered rejected if the transplant goes into cardiac arrest (page 47 of the instant specification). Is the lack of cardiac arrest in a treated animal with a particular analyte considered by applicant to be immunosuppressive agent? Does this analogy then read into human applications? A

skilled artisan would be unable to determine the meets and bounds of the claimed invention.

12. Claims 1-6,18-19 recite the phrase "a less thrombocytopenia effect" which is not defined in the claims nor in the specification. What is the thrombocytopenia effect that the new immunosuppressive agent is supposed to be "less" than? The term "thrombocytopenia effect" is not defined itself. Is it the loss of platelets in a test subject? Is it the GATA1/IL-2 IC50 ratio? Is it the GATA-1/IL-2 IC50 ratio that is greater than 5? A quantification of platelets is very different than a ratio of transcription inhibition. Which one is the skilled artisan supposed to use to gauge the thrombocytopenia effect? Is the thrombocytopenic effect the rate of decrease of platelets, as shown in table 2? Since the known immunosuppressive agents all cause thrombocytopenia, according to applicant, would a "less" thrombocytopenia effect be seen if a treated patient sees an increase in platelets? Or is it a "less" thrombocytopenia effect when compared to the thrombocytopenia effect caused by other immunosuppressive agents? Or is it a dosage effect, where different dosages of the same immunosuppressive agent causes different thrombocytopenia effects? A skilled artisan would be unable to determine the metes and bounds of the claimed invention because the skilled artisan would not know how to determine what a thrombocytopenic effect is, in order to determine if there is a reduction in that effect.

13. Claims 1 (and dependent claim 7) recite the phrase "weak GATA-1 transcription inhibitory activity." The phrase is not defined in the claim nor in the specification. How "weak" does the transcription inhibitory activity need to be in order to qualify as "weak"?

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Does a 50% reduction in GATA-1 transcription qualify as "weak?" Does a 10% reduction in GATA-1 transcription qualify as "weak". What is the "weak" transcription compared to? Is uninhibited GATA-1 transcription considered 100% or "strong" transcription? Do all cells that express GATA-1 express the GATA transcript to the same strength or percentage? A skilled artisan would be unable to determine the metes and bounds of the claimed invention.

14. Claim 18 is vague in that it recites "measuring the amount of expression of GATA-1 protein" but fails to indicate what cells are monitors for expression of the GATA-1 protein. Are these cells that endogenously express GATA-1? Which cells? A skilled artisan would be unable to determine the metes and bounds of the claimed invention.

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 1-7 and 18-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for selecting an immunosuppressive agent with a less thrombocytopenia effect, said method comprising selecting an HDAC inhibitor with potential immunosuppressant effect, by (1) measuring the immunosuppressive activity of an HDAC inhibitor; (2) measuring the IL-1 transcription inhibitory activity from a heterologous IL-2 reporter construct stably expressed in a Jurkat test cell in the

presence of the HDAC inhibitor of (1); and (3) measuring the GATA-1 transcription/expression inhibitory activity of a heterologous GATA-1 HEL cell in the presence of the HDAC inhibitor of (2); and (4) comparing the IL-2 transcription inhibitory activity with the GATA-1 transcription inhibitory activity to select an immunosuppressive HDAC inhibitor with a less thrombocytopenia effect, does not reasonably provide enablement for a method for selecting any immunosuppressive agent with a less thrombocytopenia effect, said method comprising selecting any analyte with potential immunosuppressant effect, by (1) measuring an IL-1 transcription inhibitory activity/protein expression in any test cell and (2) measuring the GATA-1 transcription/expression inhibitory activity in any test cell in the presence of the analyte, and comparing the IL-2 transcription inhibitory activity with the GATA-1 transcription inhibitory activity to select any immunosuppressive agent with a less thrombocytopenia effect. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

17. The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Teletronics*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based on a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter.,

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1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

18. 1) The nature of the invention. The invention involves a method for selecting any immunosuppressive agent with a less thrombocytopenia effect, said method comprising the said method comprising selecting any analyte with potential immunosuppressant effect, by (1) measuring an IL-1 transcription inhibitory activity/protein expression in any test cell and (2) measuring the GATA-1 transcription/expression inhibitory activity in any test cell in the presence of the analyte, and comparing the IL-2 transcription inhibitory activity with the GATA-1 transcription inhibitory activity to select any immunosuppressive agent with a less thrombocytopenia effect. The method reads on testing any analyte for thrombocytopenia effects, wherein the IL-2 and GATA-1 reporter constructs are encompassed in the same cell, and wherein any cell is the test cell. The method further reads on both in vivo and in vitro assays.

19. 2) State and unpredictability of the art. The art shows that GATA transcription factors, cells types and reporter systems, and IL-2 inhibition are complex matters. Harigae (GATA Transcription Factors and Hematological Diseases. Tohoku Journal of Experimental Medicine, 2006. 210:1-9) teaches that GATA-1 and GATA-2 transcription factors are involved in erythroid cells, and share roles in differentiation of erythroid cells. Furthermore, GATA-2 is up-regulated and compensates for a loss of GATA-1 in committed erythroid lineages (page 5). Harigae also teaches that different levels of reduced GATA-1 expression result in different disease states (page 4). Therefore, the simple lack of GATA-1 expression in the instant claims is not necessarily indicative of

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an immunosuppressant having a less thrombocytopenic effect, as GATA-2 could compensate for the loss of a GATA-1 expression.

20. Schneider-Schaulies et al (Silencing T cells or T-cell silencing: concepts in virus-induced immunosuppression. Journal of General Virology, 2006. 87:1423-1438)

teaches that immunosuppression of T cells is a target of many viral immunosuppressive regimes, allowing the virus to evade a host's immune response (see abstract).

Schneider teaches that the general mechanisms of the immunosuppression mediated by viruses are still unknown. Specifically pointing to Measles virus, Schneider-

Schaulies teaches that one way virus cause immune suppression is through cell cycle arrest of infected Cells, including T cells, but "mechanisms other than direct infection

have to be involved and to be provided in vivo by a minority of infected cells...Analysis ex vivo do not support deficiencies in IL-2 production or lack of IL-2R expression (Griffin & Ward, 1993; Moss et al, 2002). Therefore, Schneider-Schailies teaches that

immunosuppressants (in this case, the measles virus) is capable of causing

immunosuppression independent of IL-2 inhibition. He also teaches that the measles

virus does not cause the same induction of cellular mechanisms between murine and

human dendritic cells.

21. Liu et al (Stability and homogeneity of transgene expression in isogenic cells.

Journal of Molecular Medicine, 2006. 84:57-64) teaches that long term stable

expression of transgenes using a reported system is complex and not always

successful. Lui teaches that expression of the transgene is dependent on cell specific transcriptional control elements of the vectors, which still produce major variations in

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expression between different clones. Other effects include non-homogenous expression to gene silencing of the transgene (see page 57). Other transgene complexities are the unexpected expression patterns and mosaic expression of the transgene including those due to epigenetic factors. Liu teaches that these complexities arise even in isogenic clones, from a single experiment. Liu then suggests one method to help alleviate these complexities is the use of FLP recombinase. Liu further teaches that isogenic lines were obtained using the recombinases, however these cells were not phenotypically homogenous, and had loss of long term expression of the reporter genes (Page 57).

22. 3) Unpredictability of the art. The art is highly unpredictable. Without a clear understanding of GATA-1 regulation and other GATA factor compensation, nor a clear understanding of immunosuppression mediated by such factors as viruses with IL-2 independent mechanisms, and the complexity of developing cells lines with consistent and long term expression of reporter genes, a skilled artisan would have to conduct trial and error in order to test any analyte for thrombocytopenia effects, wherein the IL-2 and GATA-1 reporter constructs are encompassed in the same cell, and wherein any cell is the test cell in vivo or in vitro.

23. 4) Number of working examples. Applicants have provided a working in vivo rat transplant model wherein 9 HDAC inhibitors are tested as immunosuppressive agents, at 2 different dosages, and the rate of platelet reduction is calculated in table 2. Applicants do provide in vitro experiments comprising IL-2 and GATA-1 reporters in different cell types (Jurkat and HEL cells respectively). There is no calculation of IL-2

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and GATA-1 transcription or protein expression from in vivo in the rat transplant model after the application of an HDAC inhibitor. There is no use of IL-2 or GATA-1 reporters in vivo. There is no GATA-1/IL-2 IC50 calculation for in vivo work from the rat model. Thus the only suggestion that the IC50 ratio correlates to platelet reduction is found in figure 11. However, what exactly applicant considers a "thrombocytopenic effect" is questionable and not defined (see above). Thus applicants do not teach testing any analyte for thrombocytopenia effects, wherein the IL-2 and GATA-1 reporter constructs are encompassed in the same cell, and wherein any cell is the test cell nor using the method in both in vivo and in vitro assays. As such, a skilled artisan would have to conduct trial and error in order to practice the claimed invention.

24. 5) Amount of direction or guidance present. The applicants provide little teaching on what type of analytes can be used other than HDAC inhibitors. Applicant's reference "analytes" as "low molecular organic compounds, low molecular inorganic compounds, high molecular compounds including proteins and nucleic acids, sugars, and all other compounds, as well as their liquid mixtures, natural products, synthetic products, and extracts from animals or fungi, algae, or microorganisms" (page 26 of the instant specification) which reads on millions of potential compounds, without teaching how to choose one over the another – other then to test everything for immunosuppressive potential. Applicants only specifically test 9 HDAC inhibitors, and do not disclose the identity of those tested.

25. Applicants provide the teaching of the in vitro assay only in Jurkat cells for IL-2 assays and separate HeLa cells for GATA-1 assays in the examples. Applicants mention

that the two reporters can be included in the same cell on the same vector and any cell can be used (page 24-25) but then teaches that any using any cell is not the optimum settling, stating that "therefore, it is necessary to use as a test cell a cell substantially reflecting the state of [a] human t cell during [the] activation but not resting phase, in establishing a system for evaluating an immunosuppressive effect of an analyte using an IL-2 reporter gene" (page 25). The determination of in vivo to in vitro thrombocytopenia effect is via the correlation of a decrease in platelets compared to the G/I ratio of in vitro work, as described in figure 11 for a single HDAC inhibitor. However, what exactly applicant considers a "thrombocytopenic effect" is questionable and not defined (see above). Thus applicant do not teach testing any analyte for thrombocytopenia effects, wherein the IL-2 and GATA-1 reporter constructs are encompassed in the same cell, and wherein any cell is the test cell nor using the method in both in vivo and in vitro assays. As such, a skilled artisan would have to conduct trial and error in order to practice the claimed invention.

26. 6) Level of skill in the art. The level of skill is high. Without a teaching by applicant on a method of testing any analyte for thrombocytopenia effects, wherein the IL-2 and GATA-1 reporter constructs are encompassed in the same cell, and wherein any cell is the test cell and using the method in both in vivo and in vitro assays the skilled artisan would have to conduct trial and error in order to practice the claimed invention.

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27. 7) The breadth of the claims. The breadth of the claims are broad. The claimed invention reads on a method of testing any analyte for thrombocytopenia effects, wherein the IL-2 and GATA-1 reporter constructs are encompassed in the same cell, and wherein any cell is the test cell and using the method in both in vivo and in vitro assays the skilled artisan would have to conduct trial and error in order to practice the claimed invention.

28. Given the above analysis of the factors which the courts have determined are critical in ascertaining whether a claimed invention is enabled, including the highly unpredictable art, the scarcity of working examples provided by applicant, the lack of guidance by the applicant, and the broad nature of the invention it must be considered that the skilled artisan would have to conduct undue and excessive experimentation in order to practice the claimed invention.

Conclusion

29. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar, Ph.D. whose telephone number is 571-272-4139. The examiner can normally be reached on 8AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kam/04/10/07



DAVID GUZO
PRIMARY EXAMINER